DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-15
Baltimore, Maryland 21244-1850

Office of Clinical Standards and Quality

DATE: **August 31, 2005**

TO: Chief Executive Officer of ICD Implanting Hospital

FROM: Acting Director,
Office of Clinical Standards and Quality

SUBJECT: Data Reporting Requirements for Implantable Cardioverter Defibrillators (ICDs) for Primary Prevention

In order to obtain reimbursement, Medicare national coverage policy requires that providers implanting ICDs for primary prevention clinical indications (i.e., patients without a history of cardiac arrest or spontaneous arrhythmia) report data on each primary prevention ICD procedure. This policy became effective January 27, 2005. Details of the clinical indications that are covered by Medicare and their respective data reporting requirements are available in the Medicare National Coverage Determination (NCD) Manual, which is on the Centers for Medicare and Medicaid Services (CMS) website at www.cms.hhs.gov/manuals/103_cov_determ/ncd103c1_Part1.pdf

A provider can use either of two mechanisms to satisfy the data reporting requirement. Patients may be enrolled either in an Investigational Device Exemption trial studying ICDs as identified by the Food and Drug Administration or in the ICD Abstraction Tool, a registry developed by CMS and available through the Quality Net Exchange System (QNet). The QNet registry is currently available to all hospitals through the same network that the hospital uses to submit quality measures to Medicare for the Hospital Quality Initiative. Each hospital has a QNet Administrator with access to this system. Information regarding technical use of the QNet registry in addition to the software for the abstraction tool is available on the QNet website at www.qnetexchange.org.

Through an initial review of Medicare claims from January to August 2005, we have identified your hospital as implanting ICDs for primary prevention indications. Further, we have compared claims submitted by your facility with the QNet registry records and found that your facility does not appear to be reporting the appropriate number of records given your volume of primary prevention ICD implants.

As indicated above, reporting data for primary prevention ICD implants is a requirement of Medicare coverage. Without appropriately reported data, Medicare may be unable to approve your claims. We may also be required to take action to recoup payments already made if we discover data reporting discrepancies through our post-payment claims analysis.

I encourage you to review your facility's process for reporting ICD information to CMS to ensure that your facility's reports are filed timely and are consistent with the stipulations outlined in our national coverage determination. By securing your staff's commitment to regular use of the ICD Abstraction Tool, you will position your facility to comply with Medicare's ICD coverage policies in the future.

If you have any questions about using the ICD Abstraction Tool, please contact the QualityNet's Help Desk at (866) 288-8912 or qnetsupport@ifmc.sdps.org. For questions about Medicare's ICD coverage policies, please contact Ms. JoAnna Baldwin at (410) 786-7205 or JoAnna.Baldwin@cms.hhs.gov.

/s/
Barry M. Straube, M.D.